REMARKS

Claims 1, 6-9, and 41-50 are pending (claims 2-5 and 10-40 having been cancelled previously). Claims 1, 41 and 46 are amended herein. Support for the amendments are found throughout the specification and originally filed claims. For example, support for the amendments is found in paragraph 0085 and paragraph 0061.

35 U.S.C. § 112, WRITTEN DESCRIPTION

I. Claims 1 and 6-9

Claims 1 and 6-9 are rejected under 35 U.S.C. § 112, first paragraph for allegedly failing to comply with the written description requirement.

Claim 1 has been amended to recite "wherein the GM-CSF is selected from the group consisting of native human, canine, feline, rodent, sheep, goat, cattle, equine, swine, and non-human primate GM-CSF." The specification sets forth in paragraph 0085 that "[s]pecifically included as GM-CSFs are the natural occurring GM-CSF proteins and GM-CSFs from various species, including but not limited to, human, canine, feline, rodent, sheep, goat, cattle, equine, swine, or non-human primates."

These naturally occurring species (e.g. native) GM-CSFs are specific examples of GM-CSFs in the as-filed specification. The Examiner's allegation that the genus of claim 1 encompasses a large number of polypeptides based on 30% sequence identity to human GM-CSF is moot in light of amended claim 1. The amended claim only encompasses native GM-CSFs from species that were specifically described. It is believed that the amended claims are fully described in the as-filed application. The applicant therefore requests withdrawal of this rejection.

Claims 6-9 all depend from claim 1 and thus include all of the elements of claim 1. The applicant asserts that the written description requirement is also fulfilled for claims 6-9. For example, written description for claims 6-9 is found in paragraph 0035 and in the originally filed

claims. The applicant respectfully requests reconsideration and withdrawal of the rejection of claims 6-9.

II. Claims 41-50

Claims 41-50 are rejected under 35 U.S.C. § 112, first paragraph for allegedly failing to comply with the written description requirement.

Independent claims 41 and 46 have been amended herein. Claim 41 now recites "wherein the GM-CSF is at least 80% identical to native human GM-CSF." Claim 46 now recites "wherein the GM-CSF is at least 80% identical to native mouse GM-CSF."

The standard for written description is whether the specification conveys with reasonable clarity to those skilled in the art that the applicant was in possession of the invention now claimed. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991). Claims 41-50 comply with the written description requirement because the specification in combination with information known to the skilled artesian at the filing date conveys with reasonable clarity that the applicant was in possession of claims 41-50.

Amended independent claims 41 and 46 are both related to methods of producing oligodendrocytes from mammailian multipotent neural stem cells, comprising providing a cell culture of multipotent neural stem cells obtained from neural tissue and contacting the multipotent stem cells with an effective amount of granulocyte-macrophage stimulating factor (GM-CSF). According to the specification, GM-CSF is an oligodendrocyte promoting factor capable of increasing oligodendrocyte formation from multipotent neural stem cells (paragraph 0059). Example GM-CSFs described in the specification include native mouse and native human GM-CSFs (paragraph 0085).

The Examiner indicated that one of skill in the art would recognize proteins at least 80% identical to native human or native mouse GM-CSF. Further, because these claims have been amended to require 80% identify with the native proteins, any issue regarding a sequence similarity of at least 30% to human GM-CSF is moot. The Examiner, however, further contends that one of skill in the art would not be able to recognize proteins of the claimed genus, other than the native proteins, which would result in the production of oligodendrocytes from multipotent neural stem cells when used in the claimed methods. The applicant respectfully disagrees.

As noted above, GM-CSFs are oligodendrocyte promoting factors. Claim 41 covers a genus of GM-CSFs wherein the GM-CSFs are at least 80% identical to native human GM-CSF and claim 46 covers a genus of GM-CSFs wherein the GM-CSFs are at least 80% identical to native mouse GM-CSF.

According to the specification, a GM-CSF is an oligodendrocyte promoting factor that possesses a biological activity of the native human GM-CSF (paragraph 0060). One such biological activity of GM-CSF is its binding to any known GM-CSF receptor (paragraph 0063). Species of claims 41 and 46 therefore include native human and mouse GM-CSF and proteins 80% identical that bind to a GM-CSF receptor.

The Examiner, however, argues that one skilled in the art would not have been able to recognize effective species, other than the native GM-CSFs, because the specification does not describe the structure-function relationship of GM-CSF, which would allow one skilled in the art to recognize proteins at least 80% identical with GM-CSF's biological activity (Office Action, Page 5, lines 1-3).

The analysis of whether the specification complies with the written description requirement is conducted from the standpoint of one of skill in the art at the time the application was filed. *Wang Labs v. Toshiba Corp.*, 933 F.2d 858, 865 (Fed. Cir. 1993). Information which is well known in the art need not be described in detail in the specification. *Hybridtech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379-80 (Fed. Cir. 1986).

Because the structure-function relationship of GM-CSF was well known at the time of filing, the applicant did not need to describe it in the specification. In particular, the functional domains of GM-CSF required for binding to GM-CSF receptors to stimulate cell proliferation were well known as early as 1994. *See* Hercus, *Structure-Function Studies on Human Granulocyte-Macrophage Colony-Stimulating Factor*, University of Adelaide, Ph.D. Thesis (August 1994) (attached as Exhibit A). *See also* Shanafelt and Kastelein, *Identification of Critical Regions in Mouse Granulocyte-Macrophage Colony-Stimulating Factor by Scanning-Deletion Analysis*, Proc. Natl. Acad. Sci. 86:4872-4876 (1989) (identifying four regions within mGM-CFS that are critical to activity of the protein (page 4872, right column, first paragraph) (attached as Exhibit B).

Hercus alone describes functional domains that are critical to the cell proliferating abilities of GM-CSF (Hercus, paragraph bridging pages i and ii). Given this information, one skilled in the art could readily make numerous proteins at least 80% identical to native human or mouse GM-CSF while maintaining GM-CSF's cell proliferating activity and its ability to bind to native GM-CSF receptors. At least because binding to native GM-CSF receptors is a specific biological activity of oligodendrocyte promoting factors described in the specification written description was adequately provided for claims 41 and 46. Specifically, given the known critical regions of GM-CSF, the specification conveys with reasonable clarity that the applicant possessed the invention of claims 41 and 46.

Claims 42-45 all depend from claim 41 and thus include all of the elements of claim 41. The applicant asserts that the written description requirement is also fulfilled for claims 42-45. For example, written description for claims 42-45 is found in paragraph 0035 and in the originally filed claims. Claims 47-50 all depend from claim 46 and thus include all of the elements of claim 46. The applicant asserts that the written description requirement is also fulfilled for claims 47-50. For example, written description for claims 47-50 is found in paragraph 0035 and in the originally filed claims. The applicant respectfully requests reconsideration and withdrawal of the rejection of claims 41-50.

CONCLUSIONS

For the reasons set forth above, the applicant submits that the claims of this application are allowable. Reconsideration and withdrawal of the Examiner's rejections are hereby requested.

The applicant believes that all the issues raised by the Examiner have been addressed. However, the absence of a reply to a specific rejection, issue, or comment does not signify agreement with or concession of that rejection, issue, or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Further, the amendment of any claim herein does not necessarily signify concession of unpatentability of the claim prior to its amendment.

The required fee for a Petition for an Extension of Time for one-month is being paid concurrently herewith on the Electronic Filing System (EFS). Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

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